UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, and State of Missouri, *et al.*, Intervenor-Plaintiffs, *v.* U.S. Food and Drug Administration, *et al.*, Defendants, and Danco Laboratories, LLC, Intervenor-Defendant.	Case No. 2:22-cv-00223-Z

Joint Status Report Regarding Further Proceedings Following Supreme Court Decision

The parties in this action hereby submit the following Joint Status Report regarding further proceedings in this case following the Supreme Court's decision in *Food & Drug Administration v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024).

1. This Court previously stayed Defendants' obligation to respond to both the original Plaintiffs' Complaint and the State Intervenor-Plaintiffs' Complaint pending appellate proceedings concerning this Court's April 7, 2023 Order. *See* ECF Nos. 144, 180. The Court directed the parties "to propose – no later than two weeks after the resolution of all appellate avenues concerning this Court's April 7, 2023 Order – a new deadline for Defendants to answer or respond to both Complaints." ECF No. 180.

2. The Supreme Court issued its decision in *Alliance for Hippocratic Medicine* on June 13, 2024, and the Supreme Court's judgment issued on July 15, 2024. The Fifth Circuit issued its mandate on September 16, 2024. Accordingly, the parties have conferred and submit this joint status report.

3. **Defendants** believe that no further proceedings are necessary or warranted in this case. The Supreme Court concluded that the original Plaintiffs "lack standing to challenge FDA's actions," *All. for Hippocratic Med.*, 602 U.S. at 374, which plainly requires dismissal of their Complaint—regardless of any attempt by Plaintiffs or the State Intervenors to amend or supplement their pleadings or add new parties. The Supreme Court's decision highlighted legal defects in Plaintiffs' standing, not simply a failure to carry their evidentiary burden. Those legal deficiencies cannot be cured through an amendment to the pleadings. Additionally, the State Intervenors cannot continue with their Complaint because intervention requires an existing suit within the Court's jurisdiction, which is not present here. And the State Intervenors' claims cannot proceed as an independent suit because the States cannot satisfy venue requirements (and the States also independently lack standing). The proper course, therefore, is for this Court to immediately dismiss both existing Complaints, consistent with the Supreme Court's judgment.

In light of the Plaintiffs' and Intervenor-Plaintiffs' positions below, however, to the extent this Court is not inclined to immediately dismiss the existing Complaints, the next procedural step should be briefing a motion to dismiss the current Complaints. Given that courts must assure themselves of jurisdiction at every stage of a proceeding, this Court should not rule on any potential motion to amend or supplement the pleadings or to add new parties before determining whether jurisdiction properly exists over the current pleadings. Thus, to the extent this Court is not inclined to immediately dismiss the Complaints, Defendants propose filing a motion to dismiss as to the current Complaints by no later than 30 days following the Court's entry of a scheduling order.

4. **Intervenor-Defendant** agrees with Defendants. The Supreme Court unanimously stated in rejecting Plaintiffs' theories as insufficient to create an Article III case or controversy that "the federal courts are the wrong forum for addressing the plaintiffs' concerns about FDA's actions," and that instead "[t]he plaintiffs may present their concerns and objections to the President and FDA in the regulatory process, or to Congress and the President in the legislative process." *All. for Hippocratic Med.*, 602 U.S. at 396-397. Because there was never Article III jurisdiction over Plaintiffs' complaint, there was also never a jurisdictionally valid action into which anyone could intervene. As a result, this litigation should be over.

5. **Plaintiffs** and **Intervenor-Plaintiffs** disagree with the above positions. The Supreme Court rejected Defendants' request to "to remand with instructions that the case be dismissed or transferred to an appropriate venue." U.S. Reply Br. 14 n.3. A plaintiff has a different evidentiary burden at each stage of litigation, and the Supreme Court decided only whether the private plaintiffs amassed enough evidence to prove standing for the preliminary injunction, not whether their complaint should be dismissed, as previewed by the States' previous filings. In any event, for the reasons explained in the intervention briefs, the States have standing and could proceed even if the private plaintiffs were dismissed. And if there were a venue issue (there is not), the States could easily cure it, which would promote judicial efficiency given this Court's extensive background with the merits questions.

6. Additionally, **Intervenor-Plaintiffs** intend to file an amended complaint and any appropriate motions in conjunction with that amended complaint. This amended complaint will confirm that the States do not challenge the original 2000 approval of mifepristone, merely the FDA's actions from 2016 to 2023. The amended complaint will also provide updated facts that support Intervenor-Plaintiffs' existing theories of standing. Intervenor-Plaintiffs may also seek to amend other aspects of their complaint at the same time. Intervenor-Plaintiffs disagree with the

suggestion to proceed to a motion to dismiss now, given that any amendments may moot or alter the motion to dismiss, and Rule 15 requires that leave for a first amended complaint be freely given. Intervenor-Plaintiffs intend to move for leave to amend within 2 weeks of the filing of this status report.

September 30, 2024

Respectfully submitted,

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